PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-478WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IB2004/004185	International filing date *(day/month/year)* 17.12.2004	Priority date *(day/month/year)* 23.12.2003
International Patent Classification (IPC) or national classification and IPC INV. A61K9/48 A61K31/192		
Applicant RANBAXY LABORATORIES LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 10 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.10.2005	20.04.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Muller, S Telephone No. +31 70 340-2080

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2004/004185

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-19 as originally filed

   Claims, Numbers

   1-78 filed with telefax on 21.10.2005

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 25,26,37,38,57,58,77,78, with respect to industrial applicability

because:

☒ the said international application, or the said claims Nos. 25,26,37,38,57,58,77,78, with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*.

☒ no international search report has been established for the said claims Nos. 25,26,37,38,57,58,77,78, with respect to industrial applicability

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-78
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-78
Industrial applicability (IA)	Yes:	Claims	1-24,27-36,39-56,59-76
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

For the assessment of the present claims 25,26,37,38,57,58,77,78 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

Reasoned statement with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Cited Documents

The following documents are referred to in this communication:

D1: US-A-5 376 688 (MORTON ET AL) 27 December 1994 (1994-12-27)

D2: US-B1-6 387 400 (TINDAL STEPHEN CHARLES ET AL) 14 May 2002 (2002-05-14)

D3: WO 02/069936 A (DR. REDDY'S LABORATORIES LTD; MANDAOGADE, PRASHANT, MANOHAR; KOLHE, UJ) 12 September 2002 (2002-09-12)

2. Novelty

No document of the prior art discloses a clear ibuprofen composition comprising: a) 15-40% w/w ibuprofen, b) 30-70% w/w PEG, c) 1-10% w/w of a metal carbonate, and d) 1-10% w/w water.

Present claims 1-9,19-34,37-48,57-68,77,78 therefore appear to be new over the prior art

(Article 33(2) PCT).

No document of the prior art discloses a process for preparing a clear ibuprofen composition, comprising a) ibuprofen, b) PEG, c) a metal carbonate and d) water. Present claims 10-18,35,36,49-56,69-76 therefore appear to be new over the prior art (Article 33(2) PCT).

3. Inventive Step

Claims 1-9,19-34,37-48,57-68,77,78

D1 is considered as being the closest prior art. It discloses in example 5 a Naproxen solution comprising: a) 23,0% Naproxen, b) 5,3% of 50% KOH solution, c) 32,7% PEG, d) 32,7% Tween 80, and e) 1,2% w/w water. D1 mentions (see column 3, lines 14-22) that Ibuprofen is another suitable acidic pharmaceutical agent in a limited list of possible compounds.

Consequently, the difference between D1 and present claims 1,19,37,57,77 of the present application lies in the use of a metal carbonate instead of KOH in D1.

D3 also discloses an ibuprofen composition to be incorporated in soft gelatin capsules. In order to avoid the use of hydroxide ion species, D3 uses (see page 3, lines 2-4) alkali metal bicarbonate to carry out partial ionization of ibuprofen and subsequent conversion into alkali metal salt.

It appears that the person skilled in the art would have combined D1 and D3 to replace in the compositions disclosed in D1 the hydroxide ion species by a metal carbonate.

Independent claims 1,19,37,57,77 therefore appear not to be inventive over the prior art (Article 33(3) PCT).

Claims 10-18,35,36,49-56,69-76

D2 is considered as closest prior art. It discloses (see on column 6, lines 1-14) a process for preparing a clear ibuprofen solution comprising: a) dispersing ibuprofen in PEG, b) adding a 50% KOH/50% water solution to form a clear solution.

The difference between D2 and present claims 10,35,49,69 of the present application lies in the use of a metal carbonate instead of KOH in D1.

D3 also discloses an ibuprofen composition to be incorporated in soft gelatin capsules. In order to avoid the use of hydroxide ion species, D3 uses (see page 3, lines 2-4) alkali

metal bicarbonate to carry out partial ionization of ibuprofen and subsequent conversion into alkali metal salt.
It appears that the person skilled in the art would have applied the teaching of D3 to the process of D2 in order to prepare a clear ibuprofen composition comprising ibuprofen, PEG, a metal carbonate and water. Therefore claim 10 does not comply with Article 33(3) PCT.
Claims 35,49,69 do not appear to comprise any further technical features which lead to a non-obvious solution of a technical problem (Article 33(3) PCT).
Independent claims 10,35,49,69 therefore appear not to be inventive over the prior art (Article 33(3) PCT).

4. Industrial applicability

Claims 25,26,37,38,57,58,77,78 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
Claims 1-24,27-36,39-56,59-76 satisfy the criterion of industrial applicability set forth in Article 33(4) PCT.

We Claim:

1. A clear ibuprofen composition comprising:
   a. from about 15% to about 40% w/w of ibuprofen,
   b. from about 30% to about 70% w/w of polyethylene glycol,
   c. from about 1% to about 10% w/w of a metal carbonate, and
   d. from about 1% to about 10% w/w of water.

2. The composition according to claim 1 wherein the ibuprofen comprises from about 15% to about 35% w/w of the composition.

3. The composition according to claim 1 wherein the polyethylene glycol has an average molecular weight of about 300 to about 1000.

4. **Amended.** The composition according to claim 3 wherein the polyethylene glycol has a molecular weight of about 400.

5. The composition according to claim 1 wherein the metal carbonate comprises one or more of sodium bicarbonate, calcium carbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, magnesium carbonate, magnesium bicarbonate, or mixtures thereof.

6. The composition according to claim 5 wherein the metal carbonate comprises potassium carbonate.

7. The composition according to claim 1 further comprising one or more active ingredients, wherein the active ingredients comprise one or more of glucosamine, pseudoephedrine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

8. The composition according to claim 7 wherein the active ingredient comprises pseudoephedrine and pharmaceutically acceptable salts thereof.

9. The composition according to claim 1 wherein the composition is filled into soft gelatin capsules.

10. A process of preparing a clear ibuprofen composition, the process comprising the steps of:

a. dissolving one or more metal carbonates in water to form a solution,

b. adding ibuprofen and the solution of step (a) to polyethylene glycol with optional heating, and

c. stirring to obtain a clear solution.

11. The process according to claim 10 wherein the ibuprofen comprises from about 15% to about 35% w/w of the composition.

12. The process according to claim 10 wherein the polyethylene glycol has an average molecular weight of about 300 to about 1000.

13. **Amended.** The process according to claim 12 wherein the polyethylene glycol has a molecular weight of <u>about</u> 400.

14. The process according to claim 10 wherein the metal carbonate comprises one or more of sodium bicarbonate, calcium carbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, magnesium carbonate, magnesium bicarbonate, or mixtures thereof.

15. The process according to claim 14 wherein the metal carbonate comprises potassium carbonate.

16. The process according to claim 10 further comprising one or more active ingredients, wherein the active ingredients comprise one or more of glucosamine, pseudoephedrine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

17. The process according to claim 16 wherein the active ingredient comprises pseudoephedrine and pharmaceutically acceptable salts thereof.

18. The process according to claim 10 further comprising filling the solution into a soft gelatin capsules.

19. A soft gelatin capsule of ibuprofen, filled with a clear solution comprising:

a. from about 15% to about 40% w/w of ibuprofen,

b. from about 30% to about 70% w/w of polyethylene glycol,

c. from about 1% to about 10% w/w of a metal carbonate, and

d. from about 1% to about 10% w/w of water.

20. The soft gelatin capsule of claim 19 wherein gelatin mass of the capsule comprises gelatin, water, plasticizers, coloring agents and preservatives.

21. **Amended.** The soft gelatin capsule of claim 20 wherein the plasticizers comprises sorbitol special solution and andrisorb.

22. The soft gelatin capsule of claim 20 wherein the ratio of gelatin to water varies from 1:0.75 to 1:0.92 and the ratio of gelatin to plasticizer varies from 1:0.35 to 1:0.48.

23. The soft gelatin capsule according to claim 19 further comprising one or more active ingredients, selected from glucosamine, pseudoephedrine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

24. The soft gelatin capsule according to claim 23 wherein the one or more active ingredient is pseudoephedrine and pharmaceutically acceptable salts thereof.

25. A method of relieving one or more of pain, tenderness, inflammation and stiffness caused by one or more of arthritis and gout and pains from one or more of the common cold, backache, and pain after surgery or dental work, the method comprising administering a clear ibuprofen composition comprising:

a. from about 15% to about 40% w/w of ibuprofen,

b. from about 30% to about 70% w/w of polyethylene glycol,

c. from about 1% to about 10% w/w of a metal carbonate, and

d. from about 1% to about 10% w/w of water.

26. The method according to claim 25, wherein the composition further comprises one or more of glucosamine, pseudoephedrine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

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27. A clear ibuprofen-pseudoephedrine composition comprising:

a. from about 15% to about 40% w/w of ibuprofen,

b. from about 3% to about 6% w/w of pseudoephedrine or a pharmaceutically acceptable salt thereof,

c. from about 30% to about 70% w/w of polyethylene glycol,

d. from about 1% to about 10% w/w of a metal carbonate, and

e. from about 1% to about 10% w/w of water.

28. The composition according to claim 27 wherein the ibuprofen comprises from about 15% to about 35% w/w of the composition.

29. The composition according to claim 27 wherein the polyethylene glycol has an average molecular weight of about 300 to about 1000.

30. **Amended**. The composition according to claim 29 wherein the polyethylene glycol has a molecular weight of about 400.

31. The composition according to claim 27 wherein the metal carbonate comprises one or more of sodium bicarbonate, calcium carbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, magnesium carbonate, magnesium bicarbonate, or mixtures thereof.

32. The composition according to claim 31 wherein the metal carbonate comprises potassium carbonate.

33. The composition according to claim 27 further comprising one or more active ingredients, wherein the active ingredient comprise one or more of glucosamine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

34. The composition according to claim 27 wherein the composition is filled into soft gelatin capsules.

35. A process of preparing a clear ibuprofen-pseudoephedrine composition comprising the steps of:

a. dissolving one or more metal carbonates in water to form a solution,

a. adding ibuprofen and the solution of step (a) to polyethylene glycol with optional heating,

b. stirring to obtain a clear solution, and

c. adding pseudoephedrine or a pharmaceutically acceptable salt thereof, and stirring to obtain a clear solution.

36. The process according to claim 35 further comprising filling the solution of step (d) into a soft gelatin capsule.

37. A method of treating one or more of cough, cold, allergy, sinus and/or flu symptoms and the discomfort, pain, fever and general malaise associated with it, the method comprising administering a clear ibuprofen-pseudoephedrine composition comprising:

a. from about 15% to about 40% w/w of ibuprofen,

b. from about 3% to about 6% w/w of pseudoephedrine or a pharmaceutically acceptable salt thereof,

c. from about 30% to about 70% w/w of polyethylene glycol,

d. from about 1% to about 10% w/w of a metal carbonate, and

e. from about 1% to about 10% w/w of water.

38. The method according to claim 37, wherein the composition further comprises one or more of glucosamine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

39. A clear ibuprofen composition comprising:

a. from about 15% to about 40% w/w of ibuprofen,

b. from about 30% to about 65% w/w of polyethylene glycol,

c. from about 1% to about 10% w/w of a metal carbonate,

d. from about 1% to about 15% w/w of a surfactant, and

e. from about 1% to about 10% w/w of water.

40. The composition according to claim 39 wherein the ibuprofen comprises from about 15% to about 35% w/w of the composition.

41. The composition according to claim 39 wherein the polyethylene glycol has an average molecular weight of about 300 to about 1000.

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42. The composition according to claim 41 wherein the polyethylene glycol has a molecular weight of about 400.

43. The composition according to claim 39 wherein the metal carbonate comprises one or more of sodium bicarbonate, calcium carbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, magnesium carbonate, magnesium bicarbonate, or mixtures thereof.

44. The composition according to claim 39 wherein the surfactant is a non-ionic hydrophilic surfactant.

45. The composition according to claim 44 wherein the non-ionic hydrophilic surfactant comprises one or more of polyoxyethylene alkylethers, polyethylene glycol fatty acids esters, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene-polyoxypropylene block copolymers, polyglyceryl fatty acid esters, polyoxyethylene glycerides, polyoxyethylene vegetable oils, and polyoxyethylene hydrogenated vegetable oils.

46. The composition according to claim 39 further comprising one or more active ingredients, wherein the active ingredients comprise one or more of glucosamine, pseudoephedrine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

47. The composition according to claim 46 wherein the active ingredient comprises pseudoephedrine and pharmaceutically acceptable salts thereof.

48. The composition according to claim 39 wherein the composition is filled into soft gelatin capsules.

49. A process of preparing a clear ibuprofen composition, the process comprising the steps of:

a dissolving one or more metal carbonates in water to form a solution,

b. preparing a solution of one or more surfactants in polyethylene glycol with optional heating,

c. adding ibuprofen and the solution of step (a) to the solution of step (b), and

d. stirring to obtain a clear solution.

50. The process according to claim 49 wherein the ibuprofen comprises from about 15% to about 35% w/w of the composition.

51. The process according to claim 49 wherein the polyethylene glycol has an average molecular weight of about 300 to about 1000.

52. **Amended**. The process according to claim 51 wherein the polyethylene glycol has a molecular weight of about 400.

53. The process according to claim 49 wherein the metal carbonate comprises one or more of sodium bicarbonate, calcium carbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, magnesium carbonate, magnesium bicarbonate, or mixtures thereof.

54. The process according to claim 53 wherein the metal carbonate comprises potassium carbonate.

55. The process according to claim 49 wherein the surfactant comprises a non-ionic hydrophilic surfactant.

56. The process according to claim 55 wherein the non-ionic hydrophilic surfactant comprises one or more of polyoxyethylene alkylethers, polyethylene glycol fatty acids esters, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene-polyoxypropylene block copolymers, polyglyceryl fatty acid esters, polyoxyethylene glycerides, polyoxyethylene vegetable oils, and polyoxyethylene hydrogenated vegetable oils.

57. A method of relieving one or more of pain, tenderness, inflammation and stiffness caused by one or more of arthritis and gout and pains from one or more of the common cold, backache, and pain after surgery or dental work, the method comprising administering a clear ibuprofen composition comprising:

a. from about 15% to about 40% w/w of ibuprofen,
b. from about 30% to about 65% w/w of polyethylene glycol,
c. from about 1% to about 10% w/w of a metal carbonate,
d. from about 1% to about 15% w/w of a surfactant, and
e. from about 1% to about 10% w/w of water.

58. The method according to claim 57, wherein the composition further comprises one or more of glucosamine, pseudoephedrine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

59. A clear ibuprofen-pseudoephedrine composition comprising:

a. from about 15% to about 40% w/w of ibuprofen,

b. from about 3% to about 6% w/w of pseudoephedrine,

c. from about 30% to about 65% w/w of polyethylene glycol,

d. from about 1% to about 10% w/w of a metal carbonate,

e. from about 1% to about 15% w/w of a surfactant, and

f. from about 1% to about 10% w/w of water.

60. The composition according to claim 59 wherein the ibuprofen comprises from about 15% to about 35% w/w of the composition.

61. The composition according to claim 59 wherein the polyethylene glycol has an average molecular weight of about 300 to about 1000.

62. The composition according to claim 61 wherein the polyethylene glycol has a molecular weight of about 400.

63. The composition according to claim 59 wherein the metal carbonate comprises one or more of sodium bicarbonate, calcium carbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, magnesium carbonate, magnesium bicarbonate, or mixtures thereof.

64. The composition according to claim 63 wherein the metal carbonate comprises potassium carbonate.

65. The composition according to claim 59 wherein the surfactant is a non-ionic hydrophilic surfactant.

66. The composition according to claim 65 wherein the non-ionic hydrophilic surfactant comprises one or more of polyoxyethylene alkylethers, polyethylene glycol fatty acids esters, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene-polyoxypropylene block copolymers, polyglyceryl fatty acid esters, polyoxyethylene glycerides, polyoxyethylene vegetable oils, and polyoxyethylene hydrogenated vegetable oils.

67. The composition according to claim 59 further comprising one or more active ingredients, wherein the active ingredients comprise one or more of glucosamine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

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68. The composition according to claim 59 wherein the composition is filled into soft gelatin capsules.

69. A process of preparing a clear ibuprofen-pseudoephedrine composition comprising the steps of:

a. dissolving one or more metal carbonates in water to form a solution,

b. preparing a solution of one or more surfactants in polyethylene glycol with optional heating,

c. adding ibuprofen and the solution of step (a) to the solution of step (b),

d. stirring to obtain a clear solution, and

e. adding pseudoephedrine or a pharmaceutically acceptable salt thereof to the solution of step (d) with continuous stirring to obtain a clear solution.

70. The process according to claim 69 wherein the ibuprofen comprises from about 15% to about 35% w/w of the composition.

71. The process according to claim 69 wherein the polyethylene glycol has an average molecular weight of about 300 to about 1000.

72. The process according to claim 69 wherein the metal carbonate comprises one or more of sodium bicarbonate, calcium carbonate, potassium bicarbonate, sodium carbonate, potassium carbonate, magnesium carbonate, magnesium bicarbonate, or mixtures thereof.

73. The process according to claim 69 wherein the surfactant comprises a non-ionic hydrophilic surfactant.

74. The process according to claim 73 wherein the non-ionic hydrophilic surfactant comprises one or more of polyoxyethylene alkylethers, polyethylene glycol fatty acids esters, polyethylene glycol glycerol fatty acid esters, polyoxyethylene sorbitan fatty acid esters, polyoxyethylene-polyoxypropylene block copolymers, polyglyceryl fatty acid esters, polyoxyethylene glycerides, polyoxyethylene vegetable oils, and polyoxyethylene hydrogenated vegetable oils.

75. The process according to claim 69 further comprising one or more active ingredients, wherein the active ingredients comprise one or more of glucosamine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.

76. The process according to claim 69 further comprising filling the solution of step (e) into a soft gelatin capsule.

77. A method of treating one or more of cough, cold, allergy, sinus and/or flu symptoms and the discomfort, pain, fever and general malaise associated with it, the method comprising administering a clear ibuprofen-pseudoephedrine composition comprising:

a. from about 15% to about 40% w/w of ibuprofen,

b. from about 3% to about 6% w/w of pseudoephedrine or a pharmaceutically acceptable salt thereof,

c. from about 30% to about 70% w/w of polyethylene glycol,

d. from about 1% to about 10% w/w of a metal carbonate,

e. from about 1% to about 15% w/w of a surfactant, and

f. from about 1% to about 10% of water.

78. The method according to claim 76, wherein the composition further comprises one or more of glucosamine, codeine, paracetamol, econazole, hydrocodone, COX-2 inhibitors, alprazolam, dextromethorphan, chlorpheniramine, and pharmaceutically acceptable salts thereof.